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Display Date 9-16-04

Publication Date 9-17-04

Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P–0162]

Determination That ZOLOFT (Sertraline Hydrochloride) Tablets, 150 Milligrams and 200 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ZOLOFT (sertraline hydrochloride (HCl)) Tablets, 150 milligrams (mg) and 200 mg (new drug application (NDA) 19–839), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for sertraline HCl tablets, 150 mg and 200 mg.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was

previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ZOLOFT Tablets, 150 mg and 200 mg, are the subject of approved NDA 19–839 held by Pfizer, Inc. (Pfizer). ZOLOFT (sertraline HCl) is indicated for the treatment of major depressive disorder, obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder, premenstrual dysphoric disorder, and social anxiety disorder. Lachman Consultant Services, Inc., submitted a citizen petition dated April 5, 2004 (Docket No. 2004P–0162/CP1), under 21 CFR 10.30, requesting that the agency determine whether ZOLOFT (sertraline HCl) Tablets, 150 mg and 200 mg, were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Pfizer's ZOLOFT Tablets, 150 mg and 200 mg, were not withdrawn from sale for reasons of safety or effectiveness. Pfizer has never commercially marketed ZOLOFT Tablets, 150 mg and 200 mg. In previous instances (see, e.g., 67 FR 79640 at 79641, December 30, 2002 (addressing a relisting request for Diazepam Autoinjector)), FDA has concluded that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale. There is no indication that Pfizer's decision not to market ZOLOFT Tablets, 150 mg and 200 mg, commercially is a function of safety or effectiveness concerns, and the petitioner has identified no data or other information suggesting that ZOLOFT Tablets, 150 mg and 200 mg, pose a safety risk. FDA's independent evaluation of relevant information has uncovered nothing that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that for the reasons outlined above, ZOLOFT Tablets, 150 mg and 200 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ZOLOFT Tablets, 150 mg and 200 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than

safety or effectiveness. ANDAs that refer to ZOLOFT Tablets, 150 mg and/or 200 mg, may be approved by the agency.

Dated: 9/10/04
September 10, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S